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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	1-14-99
Publication Date	1-15-99
Certifier	J. A. W. [Signature]

Food and Drug Administration

21 CFR Part 175

[Docket No. 96F-0136]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of silver chloride-coated titanium dioxide as a preservative in polymeric coatings for polyolefin films intended for use in contact with food. This action is in response to a petition filed by Johnson Matthey Chemicals.

DATES: The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 10, 1996 (61 FR 21473), FDA announced that a food additive petition (FAP 6B4503) had been filed by Johnson Matthey Chemicals, c/o Technical Assessment Systems, Inc., The Flour Mill, 1000 Potomac St. NW., Washington, DC 20007. The petition proposed to amend the food additive

regulations in § 175.320 *Resinous and polymeric coatings for polyolefin films* (21 CFR 175.320) to provide for the safe use of silver chloride-coated titanium dioxide as a preservative in polymeric coatings for polyolefin films intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the food additive will have the intended technical effect, and (3) the regulations in § 175.320 should be amended as set forth below.

Silver chloride-coated titanium dioxide intended for use as a preservative in polymeric coatings for polyolefin films intended for use in contact with food is regulated under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) as a food additive and not as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). However, this intended use of silver chloride-coated titanium dioxide may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market food-contact articles containing silver chloride-coated titanium dioxide for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may

be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

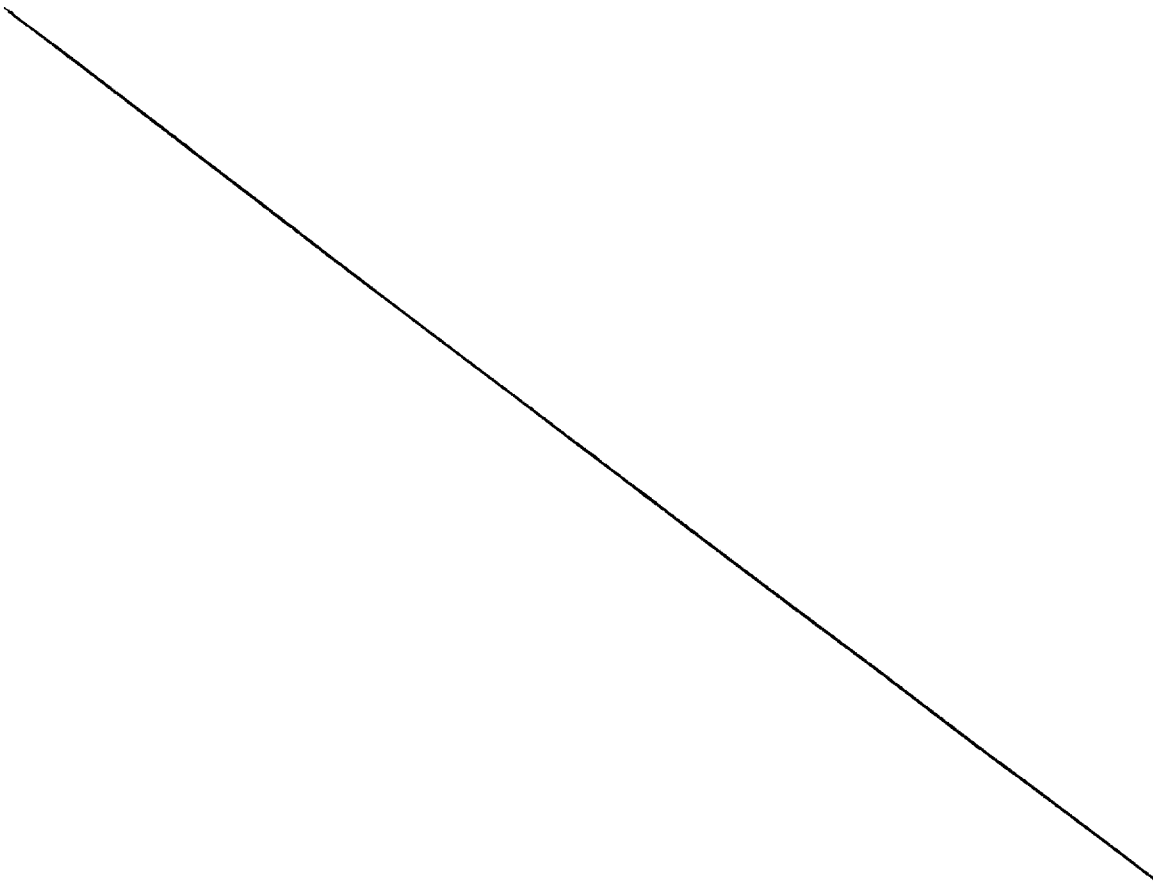
2. Section 175.320 is amended in the table in paragraph (b)(3) by adding entry “(iv)” to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

* * * * *

(b) * * *

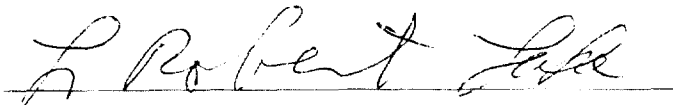
(3) * * *



List of substances	Limitations
(iv) Preservatives: Silver chloride-coated titanium dioxide.	For use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.

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Dated: 1/7/99
January 7, 1999



L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

lf [FR Doc. 96-⁹???? Filed ??-??-96⁹; 8:45 am]

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